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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,843	07/14/2000	Peter Nash	C150.12.3B	6411

7590 09/30/2002

RICHARD O. BARTZ
6750 FRANCE AVENUE SOUTH
SUITE 350
EDINA, MN 55435

EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/616,843	Applicant(s) NASH ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11 and 14-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11 and 14-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The request for a continued prosecution application (CPA) under 37 CFR 1.53(d) filed on 7/11/02 is acknowledged. 37 CFR 1.53(d)(1) was amended to provide that the prior application of a CPA must be: (1) a utility or plant application that was filed under 35 U.S.C. 111(a) before May 29, 2000, (2) a design application, or (3) the national stage of an international application that was filed under 35 U.S.C. 363 before May 29, 2000. *See Changes to Application Examination and Provisional Application Practice*, interim rule, 65 *Fed. Reg.* 14865, 14872 (Mar. 20, 2000), 1233 *Off. Gaz. Pat. Office* 47, 52 (Apr. 11, 2000). Since a CPA of this application is not permitted under 37 CFR 1.53(d)(1), the improper request for a CPA is being treated as a request for continued examination of this application under 37 CFR 1.114. *See id.* at 14866, 1233 *Off. Gaz. Pat. Office* at 48.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/02 has been entered.

3. Claims 10-11 and 14-32 are pending.

4. Claims 14-16, 27, 29 and 31 are objected to because the genus and species of an organism such as *P. anaerobius, C. sticklandii, and C. aminophilium* should be italicized. Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 10-11 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of animals to reduce the ability of immunogen to multiply, said protein-wasting immunogen is selected from the group consisting of P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, CA antigen from *C. aminophilium*, **does not** reasonably provide enablement for (1) a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of *any* "colony-forming protein-wasting immunogens" in the rumen or intestinal tracts of animals to reduce the ability of *any* immunogen to multiple, said method comprising: A) Inoculating female birds, in or about to reach their egg laying age, with *any* "particular targeted protein-wasting immunogen"; B) After a period of time sufficient to permit the production in the bird of antibody in the yolk and albumin of the eggs to the targeted immunogen, harvesting the eggs laid by the birds; C) Separating the "anti-yolk and albumin" of said eggs from the shells; D) drying said separating egg antibody yolk and albumin to provide a dried egg antibody product; E) Distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water to provide antibody-containing animal feed or water; and F) Supplying the resulting antibody-containing animal feed or water to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tract of the animal, (2) a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of *any* "colony-forming protein-wasting immunogens" in the rumen or intestinal tracts of animals to reduce the ability of *any* immunogen to multiple, said method comprising: A) Inoculating female birds, in or about to reach their egg laying age, with (2) *any* "particular targeted protein-wasting immunogen"; B) After a period of time sufficient to permit the production in the bird of antibody in the yolk and albumin of the eggs to the targeted immunogen, harvesting the eggs laid by the birds; C) Separating the "anti-yolk and albumin" of said eggs from the shells; D) drying said separating egg antibody yolk and albumin to provide a dried egg antibody product; E) Distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water to provide antibody-containing animal feed or water; and F) Supplying the resulting antibody-containing animal feed or water to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tract of the animal wherein the protein-wasting immunogen is *any* "immunogen" selected from the class of *P. anaerobius, C. sticklandii and C. aminophilium*, (3) a method of promoting the growth

of food animals by decreasing the waste of dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of any immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of said immunogen to multiply, said method comprising: A) Inoculating female birds, in or about to reach their egg laying age, with any "particular targeted protein-wasting immunogen"; B) Allowing a period of time sufficient to permit the production in the birds of antibody in the yolk and albumin of the eggs of the targeted immunogen; C) Harvesting the eggs laid by the birds; D) Separating *any* "antibody yolk and albumin" of said eggs from the shells; E) Providing a dry feed carrier materials; F) Coating said dry feed carrier material with any antibody yolk and albumin of the harvested eggs; G) Distributing the resulting said carrier material coated with any antibody yolk and albumin of the eggs substantially uniformly through an animal feed; and H) Supplying the resulting carrier material coated with any antibody yolk and albumin of said harvested eggs and animal feed to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals, (4) the said method wherein" providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp for a method of promoting the growth food animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a method of promoting the growth of the food animal by inoculating female bird with the specific immunogen such as P antigen from *P. anaerobius*, CS antigen from *C. Sticklandii*, CA antigen from *C. aminophilum*, harvest the eggs, mix and pasteurize the whole egg prior to mixing with the animal feed or water to prevent the adherence

of the specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

The specification does not teach how to use a method of promoting the growth of food animals by inoculating female birds with *any* targeted-protein wasting immunogen, in turn, the antibody produced by the birds in the yolk and the albumin would be useful in coating the dry feed carrier such as soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp that would be effective in inhibiting the ability of any organism that adhere to the rumen of or intestinal tracts of animals, thereby reducing the ability of any organism to multiply. Given the indefinite number of undisclosed immunogen, there is insufficient guidance with respect to the structure and working example that any antibody to any undisclosed immunogen is effective for inhibiting the ability of any organism to adhere to the rumen of or intestinal tracts of animals to reduce the ability of any organism to multiply. It is well known that not all immunogen or antigen on any given microorganism plays a role in adherence and colonizing the rumen or intestinal tract of any animal. Even if the immunogen is known, the antibody generated from the specific immunogen can only be specific to that immunized immunogen. For example, immunizing an egg-laying hen with P antigen from *P anaerobius* can generate antibody to the *P antigen* and under no circumstance can the hen generate antibody to the "yolk or albumin" (anti yolk and albumin) as recited in claim 10. Given the indefinite number of undisclosed immunogen, it is unpredictable that immunizing a hen with an undisclosed immunogen will have the same antibody specificity as the antibody that binds specifically to protein-wasting immunogen such as P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, CA antigen from *C. aminophilium*, in turn, would be useful for any purpose.

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Since the amino acid sequence of the immunogen is unknown, it follows that the antibody generated from any immunogen is not specific, in turn, the supply of said antibody in the animal feed or water for a method of promoting growth of food animals by

decreasing the waste of dietary protein caused by the presence of colony-forming protein wasting organisms is not enabled. Further, the specification fails to provide guidance as how to separate antibody to the yolk and albumin "anti-yolk and albumin" when the birds are inoculated with the specific immunogen such as P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, CA antigen from *C. aminophilium.*

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

7. Claims 10-11 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of (1) *any* colony-forming protein-wasting immunogens in the rumen or intestinal tracts of animals to reduce the ability of any immunogen to multiple, said method comprising: A) Inoculating female birds, in or about to reach their egg laying age, with (2) *any* particular targeted protein-wasting immunogen; B) After a period of time sufficient to permit the production in the bird of antibody in the yolk and albumin of the eggs to the targeted immunogen, harvesting the eggs laid by the birds; C) Separating the (3) anti-yolk and albumin of said eggs from the shells; D) drying said separating egg antibody yolk and albumin to provide a dried egg antibody product; E) Distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water to provide antibody-containing animal feed or water; and F) Supplying the resulting antibody-containing animal feed or water to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tract of the animal.

The specification discloses only a method of promoting the growth of the food animal by inoculating female bird with the specific immunogen such as P antigen from anaerobius, CS antigen from C. Sticklandii, CA antigen from C. aminophilum, harvest the eggs, mix and pasteurize the whole egg prior to mixing with the animal feed or water to prevent the adherence of the specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

With the exception of the specific immunogen mentioned above, there is insufficient written description about the structure associated with function of any protein-wasting immunogen. Further, it is not clear how to separate "anti-yolk and albumin" since the bird is inoculate with the specific immunogen rather than the yolk and albumin, in turn, the antibody to the specific immunogen can prevent the adherence of the specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals. Since the specification discloses only three protein-wasting immunogens such as such as P antigen from anaerobius, CS antigen from C. Sticklandii, CA antigen from C. aminophilum, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

8. Claims 10-11 and 14-32 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

The recitation of "anti yolk and albumin" in claim 10, part c page 2, line 2 of the amendment filed 5/28/02 represents a departure from the specification and the claims as originally filed. The specification discloses only antibody to CA antigen from *C aminophilium* (page 18), P antigen from *Peptostreptococcus anaerobius*, CS antigen from *Clostridium stiklandii* and the antibody in the whole egg was pasteurized and mixed with animal feed such as soy hulls or water.

The antibody "in the yolk and albumin of the eggs" in claim 10 part B, claim 14 part B, claim 15 part B, claim 16 part B has no support in the specification as filed. The specification discloses only removing the shell and the whole egg is mixed well and pasteurized using standard conditions. The whole pasteurized egg is sprayed on pellet soybean hulls (page 24, example 21). Applicant has not pointed out the support for "anti yolk and albumin" and "antibody in the yolk and albumin" come from.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 10-11 and 14-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "egg antibody yolk and albumin" in claim 10 part D and claim 14 parts D through G, claim 15 parts D through G, claim 16, parts D through G, claim 17 line 3, claim 19, line 2, claim 21, line 2, claim 23, line 2, claim 25 D through G, claim 27 part D through G, claim 29 part D through G, claim 31 part D through G, is indefinite and ambiguous. One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention. Is it egg antibody in the yolk and albumin or the albumin as an additive that functions as a stabilizer?

The recitation of "substantially prevent" in claim 17 line 6, claim 19, line 6, claim 21 line 6, and claim 23 line 6 is ambiguous and indefinite because the specification does not define the term "substantially". One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 10 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449).

The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of E coli) in livestock by

inoculating an egg laying female birds such as the hen against a selected immunogen such as bacterium E coli (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular), distributing the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed 5/28/02 have been fully considered but are not found persuasive.

Applicants' position is that (1) claims of group I comprises claims 10, 11, and 14 to 16 include the process of separating the antibody yolk and albumin material or entire contents of the eggs from the shells, the yolk and albumin material is dried to provide a dried antibody product, the product is mixed with animal feed or water which is supplied to animals. The result is that the immunogen is substantially prevented from adhering to the intestinal tract of the animal. (2) Applicants have discovered that the albumin IgM and IgA immunoglobulins increase the binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules, (3) albumin is a protein that protects the activity of the IgY type immunoglobulin. (4) Tokora et al (the '895 patent) does not teach the use of albumin IgM and IgA in conjunction with yolk IgY to inhibit adherence of targeted immunogens in the intestinal tract of an animal thereby inhibiting colony growth of the targeted immunogen and promoting growth of the food animal.

However, the arguments of counsel cannot take the place of evidences. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of albumin IgM and IgA in conjunction with yolk IgY) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the term "albumin IgM and IgA" has no support in the specification as filed.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 10-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892).

The teachings of the '895 patent have been discussed supra.

The claimed invention in claim 11 differs from the reference only by the recitation that the protein-wasting immunogen is selected from the group consisting of P anaerobius, C. stickandii and C aminophilium.

The claimed invention in claim 14 differs from the reference only by the recitation that the protein-wasting immunogen is P antigen from *P. anaerobius*.

The claimed invention in claim 15 differs from the reference only by the recitation that the protein-wasting immunogen is CS antigen from *C. sticklandii*.

The claimed invention in claim 16 differs from the reference only by the recitation that the protein-wasting immunogen is CA antigen from *C. aminophilium*.

Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilium* in livestock.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent with the immunogen such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* as taught by Krause *et al* for a method of promoting the growth of food animal such as livestock as taught by the '895 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Krause *et al* teach *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular).

Applicants' arguments filed 5/28/02 have been fully considered but are not found persuasive.

Applicants' position is that (1) claims of group I comprises claims 10, 11, and 14 to 16 include the process of separating the antibody yolk and albumin material or entire contents of the eggs from the shells, the yolk and albumin material is dried to provide a dried antibody product, the product is mixed with animal feed or water which is supplied to animals. The result is that the

immunogen is substantially prevented from adhering to the intestinal tract of the animal. (2) Applicants have discovered that the albumin IgM and IgA immunoglobulins increase the binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules, (3) albumin is a protein that protects the activity of the IgY type immunoglobulin. (4) Tokora et al (the '895 patent) does not teach the use of albumin IgM and IgA in conjunction with yolk IgY to inhibit adherence of targeted immunogens in the intestinal tract of an animal thereby inhibiting colony growth of the targeted immunogen and promoting growth of the food animal.

However, the arguments of counsel cannot take the place of evidences. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the use of albumin IgM and IgA in conjunction with yolk IgY) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the term "albumin IgM and IgA" have no support in the specification as filed.

16. Claims 17-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) as applied to claims 10-11 and 14-16 above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The teachings of the '895 patent and Krause *et al* have been discussed supra.

The claimed invention in claims 17, 19, 21, 23, 27, 29 and 31 differs from the references only by the recitation that the method including: providing a dry feed carrier material, drying said antibody yolk and albumin by coating the carrier material; with said antibody yolk and albumin, distributing said carrier material coated with said antibody yolk and albumin in animal feed or water and supplying the carrier material coated with said antibody yolk and albumin and animal feed or water to substantially prevent adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claims 18, 20, 22 and 24, 28, 30 and 32 differs from the references only by the recitation of said dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent using the hyperimmunized spray-dried egg powder as taught by the '878 patent immunized with the immunogen such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* as taught by Krause *et al* or the E coli as taught by the '895 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-

46). Krause *et al* teach immunogen such as *Peptostreptococcus anaerobius, Closteridium sticklandii, and Clostridium aminophilium* are responsible for nutrition depletion and the growth of livestock (See entire document) in livestock. The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea in livestock by adding bird antibody (IgY) against any desired immunogen of interest as a feed additive since the method of making bird antibody to any immunogen (bacteria) of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin is an obvious variation of the teachings of the references.

Applicants' arguments filed 5/28/02 have been fully considered but are not found persuasive.

Applicants' position is that (1) adalsteinsson et al (the '878 patent) does not teach coating a dry feed carrier with an antibody yolk and albumin of eggs to dry the antibody yolk and albumin. Dried egg powder mixed with animal feed rations does not dry the egg powder. (2) Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls, or cottonseed hulls. Betz et al (the '867 patent) does not teach drying of antibody yolk and albumin with soybean hulls, rice hulls, or cottonseed hulls.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The '895 patent teaches drying the separated egg antibody by the process such as spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin before or after coating is an obvious variation of the teachings of the references.

17. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of US Pat 6,086,878 (or record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The teachings of the '895 patent have been discussed supra.

The claimed invention in claim 26 differs from the reference only by the recitation of said dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the antibody from the yolk and albumin as taught by the '895 patent and the '878 patent for a method of promoting the growth of food animals by reducing the ability of the immunogen to adhere in the lumen or intestinal tracts and thereby reducing the ability of the immunogen to multiply as taught by the '895 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent

teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea in livestock by adding bird antibody (IgY) against any desired immunogen of interest as a feed additive since the method of making bird antibody to any immunogen (bacteria) of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin is an obvious variation of the teachings of the references.

Applicants' arguments filed 5/28/02 have been fully considered but are not found persuasive.

Applicants' position is that (1) adalsteinsson et al (the '878 patent) does not teach coating a dry feed carrier with an antibody yolk and albumin of eggs to dry the antibody yolk and albumin. Dried egg powder mixed with animal feed rations does not dry the egg powder. (2) Betz et al does not disclose drying of antibody yolk and albumin with soybean hulls, rice hulls, or cottonseed hulls. Betz et al (the '867 patent) does not teach drying of antibody yolk and albumin with soybean hulls, rice hulls, or cottonseed hulls.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The '895 patent teaches drying the separated egg antibody by the process such as spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin before or after coating is an obvious variation of the teachings of the references.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

20. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
September 30, 2002

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600